

Why choose a Private Ethics Committee (PEC); the latest innovative model of the Synergistic Interconnection Committee of the subgroups

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ABSTRACT

From the events that took place between the first and second half of the last century, especially during the Second World War, the need was felt to change, sometimes radically, the vision of the application of medicine, focusing attention on the patient and on its protection. A new page of Medical Ethics was therefore being written, which subsequently materialized in the creation and birth of new ethics committees, which based their principles on revised and updated laws and regulations. This happened at the level of public institutions, such as hospitals, which concentrated their attention on the lawful application of the principles of Medicine, both in the presence of therapeutic treatment and in the presence of a clinical study. The progress of the activities carried out by Experimental Science requires an update also at the level of the ethics committees, for this reason, Worldwide Consultancy & Services has introduced the latest innovation of a Private Ethics Committee (PEC), with a sphere of competence not only limited to a medical level but widely extended and for the purpose of examining and evaluating the lawful, before the start of carrying out an activity.

Keywords: Private Ethics Committee; Worldwide Ethics Committee; Synergistic Interconnection Committee; Worldwide Consultancy & Services

Introduction

The indiscriminate application of medical and non-medical practices, with the aim of obtaining a result, for collective purposes and/or for the improvement of living conditions within a state, intended as the improvement and increase of relations between members of the government of a specific state, between members of the government and the population and between members of different governments, cannot be considered as lawful, as it violates the principles of safeguard on which the constitution of a state is based, both as an independent state and as a member of a coalition (European Union, United States of America, United Arab Emirates). The term itself, "indiscriminate" is sufficient to bring down a particular project, if it does not comply with the rules of protection of single subjects, the population and/or the environment in which a particular procedure is carried out.

Both during a period of peace and during a state of tension/conflict, the principles of safeguarding remain, not surprisingly, if, during a state of war, offenses are committed by one of the two or more belligerent factions, precisely defined War crimes, international sanctions are automatically triggered for verification if war crimes have been committed. Historical examples of wrongdoing are soon verified by examining acts such as: the use of toxic gases such as Chlorine, Mustard and Lewisite during the First World War [32-37], the medical experiments conducted in the concentration and extermination camps of Nazi Germany during the Second World War [28-31], the experiments carried out in the town of Tuskegee, in Alabama (USA) in a period of time from 1933 to 1972, on a black population, with the aim of studying the effects of Syphilis [5], the Aversion Project, conducted during the political state of Apartheid, in South Africa, which aimed at the reconversion of military personnel of the SADF

(South African Defense Forces) through chemical castration and electroconvulsive treatment [6-11], the MKULTRA Project, conducted by the American intelligence services, with the aim of studying the effects of hallucinogens such as LSD on human subjects and, in particular, the experiments conducted by the Canadian psychiatrist and Donald Ewen Cameron, on the Depatterning technique, applied on women suffering from postpartum depression [12-17], replicated, at present, by the Lebanese psychiatrist Aziz al-Abub, affiliated with Hezbollah, as a method of medical torture, inside the infamous Prison 209 [18,19]. Still, in more modern times, we have the experiments conducted in internment camps, in North Korea, with gas chambers and poisons injected into prisoners and dissidents [20,21] and the persecution of practitioners of the martial art Falun Gong, in China, in order to promote the organ harvesting business from Falun Gong's practitioners [22-27]. The applicative perspective of these experiments follows what was stated at the beginning of this exposition, since, while representing research which may have led to a result which has produced an evolution from a scientific-technological point of view, they are been conducted in the absence or in clear violation of laws and regulations concerning the safety of life. For this reason, at the end of the well-known Nuremberg Trial, the Nuremberg Code was born, a set of research principles, in the ethical field, concerning experimentation, conducted on human subjects, created by the Court of the United States of America, against Rudolf Brandt (lawyer, one of the assistants of SS-Reichfuhrer Heinrich Himmler and member of Anhenerbe Organization for Ancestry Research), in one of the phases of the aforementioned Nuremberg Trial, defined as the Doctors' Trial.

This Code was divided into ten points, among which, the first and, undoubtedly the most important, stated that any research, conducted on human subjects, can be conducted with the prior authorization of the subject or subjects themselves, in turn, with prior taking into consideration all the characteristics of the experiment in question. This will be defined with the term Informed Consent [38-43]. Medical Ethics had therefore found its application within the Ethics Committees, i.e. independent bodies, made up of healthcare-medical and non-medical personnel, with the aim of protecting and guaranteeing the safety and safeguarding of subjects and/or patients, before, during and after carrying out a certain clinical practice and/or experimental research that is performed on human subjects. This definition is made explicit in the directive 2001/20/EC of the European Parliament [44-46]. Part of the definition of Ethics Committee can also be found in the principles cited in the well-known Hippocratic Oath [47-50], taken by doctors before starting their profession. In it, the deontological principles are outlined, for which the doctor himself, obliged to abide by these principles, undertakes to practice the profession for the sole purpose of protecting and not harming. the ethics committees, nowadays, for the most part, belonging to public medical structures (hospitals/health companies), are formed, in addition to medical personnel, by: a representative of the nursing sector, a biostatistics expert, a geneticist, an expert of Bioethics, a Civil Engineer, a Nutritionist, an Expert in Medical Devices, a Pharmacologist and a Pharmacist, as well as, obviously, the Medical Director of the hospital. These evaluation bodies are entrusted with the task of scrupulously examining every detail inherent in a therapy to be administered, or deciding on the feasibility of applying an experimental medical treatment. Alongside the public health ethics committees, there are also private ethics committees, which can be part of private clinics or other non-health facilities. The innovation reported by the Worldwide Ethics Committee (WEC) lies in the scope of action and coverage of this committee. It has the faculty and the possibility to deal with issues in the following

fields: medical, engineering, ecological, psychological, protection and conservation of cultural heritage, protection and conservation of environments, animal protection, and animal rights. In it, different professions and specializations are associated in a single committee, in which the basis is the defense of the principles for the fields of application listed above. With the WEC a new vision of the application of Ethics opens up, extended to a wide field, in which all the experts are interacting and interconnected, in order to achieve the common objective, i.e. Protect and Defend rights. The real innovation is represented by the synergistic integration/interconnection of the various subgroups of the committee, which are specialized in different fields, to offer expert opinions on the evaluation of "all-round" issues. Instead of taking advantage of different committees, for the evaluation and, possibly, approval of techniques, projects and methods, the WEC, thanks to the organization model with Synergic Interconnection of the Subgroups, carries out, as an individual, the work of difference, as a whole, deriving from the sum of the parts.

Materials and Methods

The WEC, equal to other ethics committees, is an independent body, however, one of the main characteristics that differentiate it from the same committees, is the fact that it is made up of highly diversified and specialized personnel in numerous professional sectors, not only concerning the bio-medicine. The second characteristic, which completely differentiates it from other ethics committees, is its functional pleiotropy, i.e. the ability of a single functional entity to deal with issues which, although they include the biomedical and healthcare fields, are very well diversified. Therefore, the new concept of Ethics, which emerges from this innovation, is the legal application of the same to all sectors, in the professional field. A single Committee including activities that, in other circumstances and fields, would be carried out by independent professional entities. Officially, the WEC began its activities on 1 December 2022 and, despite the recent birth, it has already been engaged to evaluate issues falling within the following areas:

In the field of **Medical-Health**, for the approval of a clinical study aimed at the non-surgical resolution of plantar deformation or other clinical & surgery applications;

In the field of **Business & Management**, in particular, management, training and information of personnel through business consultancy activities;

In the field of **Business and Fundraising**, for the creation of a trilateral organization, with the aim of accumulating funds for scientific and technological research in Italy, Serbia and Albania;

In the field of **Breeding and Veterinary Medicine**, with the aim of organizing safe transport for animals;

In the field of **Applied Research**, evaluated a project for the application of therapeutic mushrooms for the unconventional treatment of neurodegenerative diseases;

In the field of **Applied Micro and Nanotechnology**, for Applied Ecology and Bioremediation of environments from contamination with radioisotopes. In particular, a governmental-private cooperation is being evaluated, with the government of the independent state of Kosovo, for the management of the remediation of areas contaminated by radioisotopes, specifically, depleted uranium, deriving from the Balkan War of 1991-2001. A second possible

project, still under evaluation, would concern the management of the application of this microtechnology for the control of the contamination from Dioxin TCDD (Tetrachloroparadibenzodioxin), Furans and Methyl Isocyanate, in the soil, in inland waters, in animals and inhabitants, deriving from the accidental spill, in the industrial complex of the ICMESA of Seveso-Meda (Italy), on 10 July 1976;

In the field of **Environmental Protection and Human Health**, for the management of a project whose purpose is the use of counter-phase electromagnetic waves, for the cancellation of specific ELF frequencies (Extreme Low Frequencies) having a deleterious effect on the body and environments.

Results

Since the start of WEC activities (1 December 2022), 6 opinions have been issued:

Development of a non-surgical method for the definitive treatment of plantar deformation, Hallux Valgus, without forms of recrudescence;

Development of a company counseling system for the mitigation of internal burnout;

Development of a quality system applied to the transport of animals by land, rail, and airplane;

Integration of a therapeutic system through mushrooms for the attenuation of neuro-degenerative pathologies;

Chelating action of semiconductor microparticles, against the composite uranium mineral, Cuproslodwiskite-Uraninite-Torbernite (Uranium Salts, in particular, Uranium Phosphates), in the liquid and solid phase, detected by significant variation of electric resistance, in a liquid environment and of magnetic induction in the air;

Counter-phase sound waves for the erasing of frequencies having deleterious effects on the organism.

As things stand now, all these project proposals have been reviewed, evaluated and approved by the WEC investigation commissions. Furthermore, two of the six approved project proposals have already provided promising results regarding the application of the experimental procedure.

Discussions

What is an Ethics Committee

The Ethics Committee is an independent and private body, made up of personnel who are experts in health and non-health scientific research and management. The Ethics Committee can be characterized by its pharmacological or bio-technological vocation or ethics in the purest sense of the term or at 360°.

This characterization depends both on its original matrix, public or private, and therefore on national laws and regulations and application fields deriving from its vocation.

What does an ethics committee and in particular the WEC do

The main function of an ethics committee is to provide third parties, upon request, with opinions, evaluations or guidelines from an ethical point of view regarding medical practices of treatment or medical, scientific and management research.

In particular, the tasks of the WEC are ethical consultancy in the formulation of clinical and healthcare practice, in the formulation and evaluation of research and diagnostic or therapeutic experimentation protocols and the promotion of training and awareness of bioethics and related management aspects with respect to the concept of ethics.

Why a private ethics committee

Since their scientific-pharmacological or bio-technological vocation is often the limit of public ethics committees, as mentioned earlier, they are linked to filters inherent in the legitimacy aspects of scientific research on human and/or animal samples, religious and moral aspects. The latter can even be traced back to the application of the various Geneva Conventions of the United Nations.

In 100% of cases the Ethics Committee is a must for some sectors such as chemical-pharma, or the hospital sector of organ transplants or in bio-technological scientific research laboratories.

However, there are many other sectors that could need a super-partes third party comparison on applied or theoretical scientific research protocols, on market research protocols, on marketing actions linked to the production of certain mass goods whose effects do not visible could lead to very important damage to the community. See, for example, the placing on the market of products that could generate phenomena of psycho-genetic manipulation in the younger generations or unnatural behavioral aspects in animals.

Here the choice to create an ethics committee exclusively dedicated to the private sector dedicated to expressing opinions, assessments or guidelines on request in the areas of ethical principles defined by the Board of Worldwide Consultancy & Services.

The principles of the Worldwide Ethics Committee

The WEC has the responsibility to ensure that the experimental practices and related activities are full "Compliance" with the concepts of ethics, lawfulness, and morality, beyond political, moral and religious principles in respect of inclusion among human beings and animals.

It does not benefit from dedicated private, let alone public, funds. All WEC revenues are devoted to its livelihood and in the development and implementation of assessment tools then fund the logistics of WEC members during on-site verification missions to applicants to assess on-site activities and outcomes.

All members of the WEC, internal and external, cannot participate or request opinions if they collaborate with the requesting companies. There are no exceptions.

In this context, the WEC as an integral part of Worldwide Consultancy & Services has adopted since its creation the Transparency Register of the Italian Ministry of Economic Development (register no. 2021-20162795-88).

For the assessment and decision regarding the admissibility of the trials, the WECs refer to legal documents and instruments shared at an international level as well as to all the regulations in force in this area at a national and international level.

For the ethical aspects, the main references are the Declaration of Helsinki [1] and the Convention on Human Rights and Biomedicine [2] (of Oviedo).

Both documents underline, among other things, the importance of the primacy of the well-being of the person over the interests of research and informed consent. To evaluate drug trials, the WEC can also refer to the indications contained in the Standards of Good Clinical Practice (GCP) and in the Guidelines of the European Medicines Agency (EMA) [1,3,4]. The areas and limits of the Worldwide private ethics committee.

The areas of the WEC are those of issuing opinions, assessments and guidelines in the field of scientific-technological, economic, phyto-sanitary, management, marketing and production research as well as the safety of the subjects involved in an active or passive, direct way or indicted.

It does not provide opinions or evaluations on pharmacological or biological experiments of chemical or natural origin dedicated to humans or animals.

Conclusions and Future Proposals

Why choose the Worldwide ethics committee?

[1] Because it is a super partes body not linked to scientific currents (see for example the negationist), religious, political and economic currents.

[2] Because it has no interest in going against its principles as these are the true value of the committee expressed by its members.

[3] Because it has no public or private ties.

[4] Because Worldwide's Mission is to create a better future that passes for today's people and not only for those of tomorrow.

Declarations

Source of Funding

The project is fully self-financed by Worldwide Consultancy & Services.

Conflicts of Interests

All WEC members have signed a disclaimer stating that there is no conflict of interest.

Consent for publication

We declare that we consented for the publication of this research work.

Acknowledgment

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References

[1] WMA declaration of Helsinki – Ethical principles for medical research involving human subjects.

[2] Convention for the Protection of Human Rights and Human Dignity with regard to Applications of Biology and Medicine: Convention on Human Rights and Biomedicine (ETS No. 164).

- [3] UN Convention on Prohibitions or Restrictions on the Use of Certain Conventional Weapons which may be deemed to be Excessively Injurious or to have Indiscriminate Effects.
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